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EXAMINER

SUTTON, DARRYL C

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Applicant's arguments

Claim Rejections - 35 USC § 112

Claims 1-18 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that Example 2 was published in a highly reputable, peer reviewed periodontal research journal. This level of scrutiny certainly demonstrates that the clinical study was well designed to demonstrate the desired endpoints, as well as addressing the variables associated with the study. Therefore, the data generated would enable one of skill in the art to conclude, as did Applicants, that the non-aqueous composition is useful for preventing plaque or plaque build-up and for preventing gingivitis.

The Examiner disagrees.

While the Examiner agrees that some of the variables argued were compensated for by the study design, Example 2 does not provide enablement for the claimed methods of preventing plaque, plaque build-up and gingivitis. Applicant's own specification discloses that "The study demonstrated that a dentifrice containing bioactive glass in a non-aqueous formulation as detailed significantly improved oral

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health as measured by a reduction in gingival bleeding and reduction in supra-gingival plaque compared with bioactive glass free dentifrice over the six week study period," see paragraph [0072]. Accordingly, this "reduction" in bleeding and supra-gingival plaque does not provide enablement for the prevention of plaque, plaque build-up or gingivitis, but only for a reduction in bleeding and supra-gingival plaque.

Claim Rejections - 35 USC § 103

Applicants argue that the invention is directed to methods of preventing or reducing plaque or plaque build-up and of preventing or reducing gingivitis and neither Gates or Litkowski teach or suggest such methods. One of skill in the art would not have been motivated by the teaching of Litkowski to modify the composition of Gates by using an alternate abrasive because Gates was already using the preferred abrasive taught by Litkowski. At best, one skilled in the art would expect such a substitution to produce a composition that whitens teeth.

The Examiner disagrees.

A prior art reference is evaluated for all that it reasonably suggests, and is not limited to preferred embodiments or working examples. Accordingly, it would have been obvious for one of ordinary skill would to substitute the alternate abrasive, i.e. bioactive glass.

Since the rationale for modifying the prior art teachings relied upon by the examiner need not be the same as that provided by applicant, the fact that applicant

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has recognized another advantage (here a method of preventing or reducing plaque, plaque build-up or gingivitis) which would flow naturally from following the suggestion of the prior art (here because at the time of the invention the working mechanism of the antibacterial activity of bioactive glass, i.e. its ability to reduce the viability of detrimental oral microorganisms and gingivitis, was known in the art, i.e. Stoors et al. US 6,190,643, as cited in the Non-final office action dated 10/27/2009, page 10) cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants argue that Storrs teaches an aqueous composition containing preferably 40-80% of bioactive glass for achieving its use, i.e. preventing gingivitis. Effectively, this is a teaching away from the instant invention, which is a non-aqueous composition comprising about 0.25 to about 10% of bioactive glass particles.

The Examiner disagrees.

Stoors et al. was used as art not relied upon but considered pertinent to applicant's disclosure. It was used to teach the activity of bioactive glass and not for any particular composition or amounts. One of ordinary skill would reasonably assume that the activity of bioactive glass is not dependent on the amount used since each particle would possess the inherent activity based on its structure. However, Stoors discloses preferably "about" 40% to 80% and the instant application discloses "about" 0.25% to about 10% and about 2% to about 5%. Neither reference provides disclosure as to the definition of "about."

For the purposes of applying prior art and absent a limiting definition by the specification, the term “about” will be interpreted broadly. The scope of term may be considerable where the components of the respective compositions merely perform substantially the same function in substantially the same manner:

As we have held, because of the way that the patentee has used the word ‘about’ in the context of the written description and the claims in this case construction of the term ‘about 30 um’ requires consideration of the purpose or ‘criticality’ of the limitation to the invention... As our construction makes clear, ‘about 30 um’ encompasses particle diameters that perform the same function, in the same way, with the same result as the 30 um particles, as long as those diameters are within the range left open by the specific disclosures of the specification.

Cohesive Technologies v. Waters Corp., 88 USPQ2d 1903, 1916 (Fed. Cir. 2008).

Further, Gates discloses “about 5% to about 30% of abrasive which overlaps the amounts of the instant claims. Accordingly, the disclosure of Stoors et al. does not teach away from the instant invention. One of ordinary skill would reasonably expect the about 5 to 30% of bioactive glass of the composition suggested by combining Gates and Litkowski to perform all activities based on its structure, so it would reasonably be expected to whiten teeth as well as reducing the viability of detrimental oral microorganisms or gingivitis.